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EXAMINER

JANG, CHRISTIAN YONGKYUN

ART UNIT

PAPER NUMBER

4153

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/506,872	Applicant(s) GIRON ET AL.	
	Examiner CHRISTIAN Y. JANG	Art Unit 4153	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-109 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66-109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/8/05, 12/19/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-65 have been cancelled in preliminary amendment filed on 09/03/2004.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

4. Claim 82 is objected to because of the following informalities: Lack of antecedent basis for "said part". Appropriate correction is required. For purposes of examination, it will be understood that "said part" is equivalent to "a part"
5. Claim 106 is objected to because of the following informalities: "plateau volume of said breath" should be changed to "plateau value of the waveform of said breath". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 105 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 105 claims a volatile organic compound as part of the system for determining the concentration of a volatile organic compound. The specifications disclose the exhaled air as the only source of the VOC. It is noted that the disclosure teaches a VOC absorbing “trap” as claimed in claim 107, which applicant is advised to bring into the base claim 105.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 108 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: prior to step 1, “measuring a first volume of said species over a unit of time by means of said breath test”. In addition, the last step should be revised from “said second concentration measured is representative of the volume of said species” to “said second concentration measured is representative of the volume of said species over said unit of time”.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 66, 67, 69, 71-74, 76-79, 84, 86-89, 91, 95, 96, 98, 99, 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemelson (USP #5,787,885).

12. As to claim 66, Lemelson teaches a system for collecting a plurality of samples of breath of a subject (Abs) comprising:

a breath conduit adapted to convey breath from the subject (11);

a plurality of sample containers for collection of said plurality of samples (20);

a sample distributor which directs different predetermined samples of said breath to different ones of said plurality of sample containers (col 5, 30-35).

13. As to claim 67, Lemelson teaches a system according to claim 66 and also comprising a controller, and wherein said different predetermined samples of said breath are directed to different ones of said plurality of sample containers according to said controller (col 5, 32-35).

14. As to claim 69, Lemelson teaches a system according to claim 66 wherein said sample distributor directs said samples at predetermined times (col 7, lines 47-52).

15. As to claim 71, Lemelson teaches a system according to claim 69 wherein said predetermined times are determined by a characteristic of said breath of the subject (col 7, lines 17-21).

16. As to claim 72, Lemelson teaches a system according to claim 71 wherein said characteristic of said breath is at least one of the carbon dioxide concentration, the

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oxygen concentration, the excess pressure, the temperature, the humidity, the flow rate and the sound of said breaths (col 6, line 65 to col 7, line 4).

17. As to claim 73, Lemelson teaches a system according to claim 69 wherein said predetermined times are determined by at least one physiological characteristic of the subject (col 6, lines 14-17).

18. As to claim 74, Lemelson teaches a system according to claim 73 wherein said at least one characteristic of the subject is selected from a group consisting of the subject's breath composition, breath rate, heart rate, blood pressure, gastric pH value and temperature (col 6, lines 14-17).

19. As to claim 76, Lemelson teaches a system according to claim 66 and wherein said breath conduit comprises a breath tube through which the subject provides breath by blowing (11).

20. As to claim 77, Lemelson teaches a system according to claim 76 and also comprising a one way check valve for directing said breath samples from said breath tube towards said plurality of sample containers (col 2, lines 27-31).

21. As to claim 78, Lemelson teaches a system according to claim 66 and also comprising
a breath analyzer for determining a characteristic of said breath (col 6, lines 14-23); and
a valving system to select at least part of said breath for transfer to said sample a distributor, according to said characteristic of said breath (col 5, lines 39-42).

22. As to claim 79, Lemelson teaches a system according to claim 67 and also comprising

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a breath analyzer for determining a characteristic of said breath (col 6, lines 14-23); and a valving system to select at least part of said breath for transfer to said sample distributor, according to said characteristic of said breath (col 5, lines 39-42).

23. As to claim 84, Lemelson teaches a system according to claim 79 wherein said controller causes said sample distributor to direct said samples at predetermined times (col 7, lines 47-52).

24. As to claim 86, Lemelson teaches a system according to claim 84 wherein said predetermined times are determined by a characteristic of said breaths of the subject (col 7, lines 17-21).

25. As to claim 87, Lemelson teaches a system according to claim 86 wherein said characteristic of said breath is at least one of the carbon dioxide concentration, the oxygen concentration, the excess pressure, the temperature, the humidity, the flow rate and the sound of said breaths (col 6, line 65 to col 7, line 4).

26. As to claim 88, Lemelson teaches a system according to claim 84 wherein said predetermined times are determined by a physiological characteristic of the subject (col 6, lines 14-17).

27. As to claim 89, Lemelson teaches a system according to claim 88 wherein said at least one physiological characteristic of the subject is selected from a group consisting of the subject's breath composition, breath rate, blood pressure, gastric pH value and temperature (col 6, lines 14-17).

28. As to claim 91, Lemelson teaches a system according to claim 66 and wherein at least one of said sample containers has rigid walls and is evacuated before collection of

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said samples (col 2, lines 39-46). Although Lemelson does not specify a container with rigid walls, the use of a technique to controllably flush and clean residual gas is indicative of a container that has not started out deflated, and thus has the rigidity to sustain an internal volume or space.

29. As to claim 95, Lemelson teaches a system for collecting a plurality of samples of breath of a subject comprising:

a breath conduit adapted to convey breath from the subject (11);

a valving system to select at least part of said breath, said valving system being actuated according to a physiological characteristic of the subject (col 5, lines 39-42);

a plurality of sample containers for collection of said plurality of samples (20);

a sample distributor which directs different predetermined samples of said breath to different ones of said plurality of sample containers (col 5, 30-35).

30. As to claim 96, Lemelson teaches a system according to claim 95 wherein said at least one characteristic of the subject is selected from a group consisting of the subject's breath composition, breath rate, heart rate, blood pressure, gastric pH value and temperature (col 6, lines 14-17).

31. As to claim 98, Lemelson teaches a system according to claim 95 and wherein said breath conduit comprises a breath tube (11).

32. As to claim 99, Lemelson teaches a system according to claim 98 and also comprising a pressure sensor for determining the pressure of said breath (Abs), and wherein said valving system is actuated according to said pressure of said breath (col 2, lines 32-39).

33. As to claim 104, Lemelson teaches a system according to claim 95 and wherein at least one of said sample containers has rigid walls and is evacuated before collection of said samples (col 2, lines 39-46).

34. Claims 108 & 109 are rejected under 35 U.S.C. 102(b) as being anticipated by Mault (USP #5,179,958).

35. As to claim 108, Mault teaches a method of determining, in a breath test of a subject, the change in volume of a species in the subject's breath, comprising the steps of:

measuring a first volume of said species over a unit period of time by means of said breath test (col 4, lines 42-46);

measuring a first concentration of said species on the breath of the subject by means of said breath test (col 4, lines 55-57);

measuring a second concentration of said species in the breath of the subject by means of said breath test (col 4, lines 55-57);

monitoring a physiological parameter of the subject related to the metabolic rate of the subject, for change in said parameter between the measuring of said first concentration and said second concentration (col 4, lines 55-57); and

adjusting said second concentration according to change determined in said physiological parameter, such that said second concentration measured is representative of the volume of said species over said unit time in the subject's breath (col 4, lines 62-66).

36. As to claim 109, Mault teaches the method of claim 108, wherein said physiological parameter of the subject is at least one of the pulse rate of the subject, the integrated area under a capnographic measurement of the subject's breath, and the breath flow rate of the subject (col 4, lines 62-66).

Claim Rejections - 35 USC § 103

37. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

38. Claims 75 & 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885) in view of Dietz (USP #5,005,571).

39. As to claim 75 & 97, Lemelson discloses the invention substantially as claimed. However, Lemelson does not disclose a breath conduit in the form of an oral/nasal cannula.

Dietz teaches a oral/nasal cannula (Abs) for the purpose of use in a breathing monitoring apparatus (Abs).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lemelson with the cannula as taught by Dietz in order to allow for the use of the device wherein the user no longer has to actively engage the device.

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40. Claims 68, 70, 85, 100-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885).

41. As to claims 68 & 100, Lemelson discloses the invention substantially as claimed. Lemelson does not teach a sample distributor which is operated manually. However, Lemelson does disclose an automatic sample distributor and it would not be beyond the ability of one of ordinary skill in the art to utilize a manually operated sample distributor when the end result is equivalent.

42. As to claims 70 & 85, Lemelson discloses the invention substantially as claimed. Lemelson does not teach that the predetermined times are at fixed time intervals. However, it is the examiner's position that it would not be beyond the ability of one of ordinary skill in the art to recognize that gas samples collected at fixed time intervals would allow comparative analysis without a time-dependent variable. Thus, it would be obvious to one of ordinary skill in the art to modify Lemelson with a fixed time interval mechanism in order to increase the accuracy of the device.

43. As to claim 101, Lemelson teaches a system according to claim 99 and also comprising a controller causing said sample distributor to direct said different predetermined samples to said different ones of said plurality of sample containers (74).

44. As to claim 102, Lemelson teaches a system according to claim 101 wherein said controller prompts the subject at predetermined times to provide breath by blowing (col 8, lines 46).

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45. Claims 80-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885) in view of Hoberman (USP #5,159,934).

46. As to claims 80 & 81, Lemelson discloses the invention substantially as claimed. Although Lemelson discloses various chemical, photoelectric, and bio-sensors, he does not specifically disclose a capnographic analyzer.

Hoberman teaches a miniature sensor for capnography (Abs) for the purpose of rapid, up-to-date readings of CO₂ concentration in the patient air stream (Abs). In addition, the examiner notes that the analysis of CO₂ gas from patient exhaled breath is one of the most common and well known analytical techniques for patient respiration diagnosis including some forms of lung disease and various other conditions.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lemelson with the capnography sensor taught by Hoberman in order to specify the use of the device for the analysis of CO₂ concentration.

47. As to claims 82, a capnography sensor, as taught by Hoberman, by definition measures the carbon dioxide concentration.

48. Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885) and Hoberman (USP #5,159,934) and in further view of Casparie et al. (USP #5,069,220).

49. As to claim 83, Lemelson and Hoberman discloses the invention substantially as claimed. However, Lemelson and Hoberman does not disclose a system wherein the

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breath is collected when CO₂ concentration is at the plateau value of its waveform, such that alveolar air is sampled.

Casparie teaches the use of exhaled breath when carbon dioxide concentration reaches a plateau level (col 1, lines 21-23) for the purpose of most accurate determination of blood gas concentration.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lemelson and Hoberman to begin collection when carbon dioxide level reaches a plateau in order to increase the accuracy of the device.

50. Claims 90 & 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885) in view of Opekun, Jr. et al. (USP #5,140,993).

51. As to claims 90 & 103, Lemelson discloses the invention substantially as claimed. However, Lemelson does not disclose a sample container in the form of a flexible bag.

Opekun teaches a flexible, inflatable plastic bag (Abs) for the purpose of collecting a breath sample.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lemelson with Opekun in order to increase the efficiency of the device.

52. Claims 92-94, 105-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885) and Hoberman (USP #5,159,934) and further in view of Daniels et al. (USP #6,099,481).

53. As to claim 92, Lemelson and Hoberman discloses the invention substantially as claimed. Lemelson and Hoberman teaches all the limitations of claim 80, which claim 92 is dependent upon. However, Lemelson and Hoberman does not disclose a valving system adapted to direct breath exhaled when said CO₂ concentration is at the plateau for one of said container and breath inhaled when said CO₂ concentration is at the baseline into a second one of said sample containers.

Katzman teaches respiratory measurements which includes carbon dioxide elimination, airway dead space, and physiologic dead space which clearly shows the plateau during exhalation and the baseline for inhalation for the purpose of deciphering the volume of CO₂ elimination and alveolar volume (col 8 line 61 to col 9 line 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lemelson and Hoberman to capture breath samples during these baseline and plateau periods in order to enable to machine to decipher such physiological parameters as CO₂ elimination and alveolar volume.

54. As to claim 93, Lemelson, Hoberman, and Daniels discloses the invention substantially as claimed. Lemelson teaches sample containers which absorbs a predetermined gas of said breath of the subject (col 6, lines 37-43). Lemelson, Hoberman, and Daniels fails to teach a heater for expelling said predetermined gas of said breath of the subject. However, Lemelson recognizes the importance of cleaning

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out the chambers, utilizing a water trap and flushing mechanism to clean out the chambers (Fig. 2, 29). In addition, the expulsion of gas from a container by means of using the properties of thermal expansion is a well known technique in the field. It is the examiner's position that it would not be beyond the ability of one of ordinary skill in the art to modify Lemelson with a heated chamber in order to remove residual sample gas molecules which may adversely affect future usage of the container as an alternative to the existing liquid/water trap.

55. As to claim 94, Lemelson, Hoberman, and Daniels discloses the invention substantially as claimed. Lemelson teaches that said predetermined gas is a volatile organic compound. Although Lemelson does not explicitly state the phrase "volatile organic compound", the examiner notes that there is no limiting definition within the applicant's disclosure as to the limitations of the phrase. Thus, the examiner is taking the broadest reasonable definition of the phrase, in light of the disclosure, wherein "volatile organic compound" may mean any substance detectable from human expired breath that have high enough vapor pressure to vaporize into a gaseous form. Since Lemelson teaches that his teachings can be used to automatically analyzing the chemical contents within the breath of living beings for analysis of a variety of conditions and diseases of said living being, the examiner regards Lemelson to teach the limitations of the claim.

56. Claims 105-107 are rejected under an aggregate of rationale as expounded above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN Y. JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon. - Thurs. (7AM-5PM) EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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1/23/2008

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